IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ANDRULIS PHARMACEUTICALS CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 13-1644 (RGA)
	)	
CELGENE CORPORATION,	)	
	)	
Defendant.	)	

OPENING BRIEF IN SUPPORT OF CELGENE CORPORATION'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT FOR FAILURE TO STATE A CLAIM

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NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff Andrulis Pharmaceutical Corporation ("Andrulis") filed a Complaint against Defendant Celgene Corporation ("Celgene") asserting infringement of U.S. Patent No. 6,140,346 ("'346 patent"). (Ex. 1, D.I. 1.)[1] Although the Complaint purports to allege direct, contributory, induced, and willful infringement of the '346 patent, it contains only conclusory allegations and formulaic recitations of the elements of direct, contributory, and willful infringement, which fail to meet the minimal notice pleading requirements of Federal Rule of Civil Procedure 8(a). For the active inducement claim, the Complaint fails to allege facts (beyond conclusory allegations) that support a plausible inference of the elements of such a claim, as the law requires. Having failed to state a claim for which relief may be granted, Andrulis's Complaint should be dismissed under Federal Rule of Civil Procedure 12(b)(6).

SUMMARY OF ARGUMENT

The pleading standards of Federal Rule of Civil Procedure 8(a) were recently articulated in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). As the Supreme Court held, Rule 8 "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570).

Here, Andrulis has failed to meet these basic pleading requirements. With respect to direct infringement, the claims of the '346 patent require either (1) compositions comprising both thalidomide and an alkylating agent, or (2) a method of treating neoplastic diseases using that combination of drugs. (Ex. 1, D.I. 1-1, Ex. A, '346 patent at 17:17–18:21 (claims 1–3).) Yet,

[1] Exhibit 1, attached for the Court's convenience, includes the Complaint (D.I. 1), the '346 patent (D.I. 1-1, Ex. A) and cited portions of Complaint Exhibits B–D (D.I. 1-1, Exs. B–D).

Andrulis never alleges that Celgene makes, uses, or sells the required composition comprising both thalidomide and an alkylating agent, or that Celgene performs the recited method. As such, Andrulis's claim for direct infringement (Ex. 1, D.I. 1 at ¶ 84) must be dismissed.

Andrulis's contributory infringement claim fares no better. A viable claim for contributory infringement would require, *inter alia*, allegations that: (1) the products at issue lack substantial non-infringing uses; and (2) Celgene knew that those products were especially made or adapted for infringing use. 35 U.S.C. § 271(c); *see also In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337 (Fed. Cir. 2012). Andrulis fails to allege either element. To the contrary, Andrulis's Complaint establishes that the products at issue do have substantial non-infringing uses and that they are not especially made or adapted for an infringing use. In particular, Andrulis's allegations confirm that none of the FDA-approved uses of the products at issue involves a combination of both thalidomide (or its alleged equivalent) with an alkylating agent, the only alleged use accused of infringing the '346 patent. (Ex. 1, D.I. 1-1, Exs. B–D.) Thus, Andrulis's contributory infringement claim (Ex. 1, D.I. 1 at ¶ 84) fails as a matter of law and must be dismissed.

Andrulis also fails to state a claim that Celgene has actively induced infringement of the '346 patent. Among other things, Andrulis must allege facts that plausibly support inferences that Celgene affirmatively induced a direct infringement, specifically intended to cause infringement, and knew that the allegedly induced acts constituted infringement. 35 U.S.C. § 271(b); *see also Bill of Lading*, 681 F.3d at 1339; *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327–29 (Fed. Cir. 2009). Yet the active inducement claim is based on a general and conclusory allegation that Celgene purportedly encouraged doctors to treat multiple myeloma, a blood cancer, with a combination of lenalidomide (Revlimid®) or thalidomide (Thalomid®) and

an alkylating agent, melphalan (Alkeran®). (Ex. 1, D.I. 1 at ¶ 85.) Such a conclusory allegation is insufficient to support the elements of an active inducement claim. *See Iqbal*, 556 U.S. at 678.

Andrulis's remaining factual allegations (Ex. 1, D.I. 1 at ¶¶ 54–74) do not plausibly show that Celgene induced doctors to combine Thalomid® or Revlimid® with an alkylating agent (which Andrulis alleges would be an off-label use for either drug); nor do they plausibly support the knowledge and specific intent elements of active inducement. Andrulis's allegations are either conclusory, irrelevant, or consistent with Celgene's marketing of the products at issue for non-infringing approved uses. Indeed, the Complaint is tellingly devoid of any non-speculative allegations of when, where, or how Celgene allegedly induced (and specifically intended to induce) someone to infringe any claims of the '346 patent. Accordingly, Andrulis's inducement claim should be dismissed.

Finally, Andrulis fails to state a claim for willful infringement. Andrulis offers only formulaic boilerplate about actual or constructive knowledge of an objectively-defined risk of infringement. Andrulis makes no allegation of any pre-filing knowledge or conduct by Celgene that would support a finding that it acted recklessly. The Court should dismiss Andrulis's conclusory willfulness claim.

For all of these reasons, Celgene respectfully requests that the Court dismiss the Complaint under Rule 12(b)(6).

STATEMENT OF FACTS

A. The '346 Patent

Claims 1 and 3 of the '346 patent require pharmaceutical compositions that contain both thalidomide and an alkylating agent. (Ex. 1, D.I. 1-1, Ex. A at 17:17–18:3, 18:13–21.) Andrulis does not allege that Celgene has ever sold any product that contains both of these two active

ingredients.[2] The only other claim in the '346 patent—claim 2—involves a method of treatment requiring a combination of thalidomide and an alkylating agent:

> A method for the treatment of neoplastic diseases in a mammal which comprises administering to said afflicted mammal enhanced therapeutically-effective amounts of ***thalidomide in combination with effective amounts of other alkylating agent*** selected from the group consisting of mechlorethamine, cyclophosphamide, ifosamide, melphalan, chlorambucil, busulfan, thiotepa, carmustine, lomustin, cisplatin, and carboplatin wherein said neoplastic diseases are sensitive to said enhanced combination.

(*Id.* at 18:4–12 (emphasis added).) However, Andrulis does not allege that Celgene administers compositions to patients (whether in the recited combination or otherwise).

B. The Products At Issue

Celgene is a global biopharmaceutical company involved in developing and marketing pharmaceutical products. (Ex. 1, D.I. 1 at ¶ 4.) The use of three products is at issue here: (1) Thalomid®, marketed by Celgene since 1998 (*id.* at ¶¶ 19–20); (2) Revlimid®, marketed by Celgene since 2005, (*id.* at ¶¶ 25–26); and (3) Alkeran®, marketed by Celgene from 2003–2009 (*id.* at ¶ 17).

1. Thalomid® (Thalidomide)

Celgene sells thalidomide for prescription use under the brand name Thalomid®. (Ex. 1, D.I. 1 at ¶ 19; *see also* Ex. 1, D.I. 1-1, Ex. C.) In 1998, the FDA approved Thalomid® to treat symptoms associated with leprosy. (Ex. 1, D.I. 1-1, Ex. C at 1.) In 2006, the FDA approved Thalomid®, when used in combination with dexamethasone, for treating patients with newly-

[2] Andrulis seemingly would concede that Celgene does not sell any products that infringe claims 1 or 3, but the Complaint does not specify which claim(s) are asserted. (*See* Ex. 1, D.I. 1 at ¶¶ 81, 84–85 (referring to "one or more claims of the '346 patent").) Even if Andrulis asserts infringement of claims 1 or 3, however, the Complaint includes no allegations that would support such claims.

diagnosed multiple myeloma. (*See id*.) Andrulis does not allege that use of Thalomid® according to any of its FDA-approved indications infringes the ’346 patent.

2. Revlimid® (Lenalidomide)

Celgene sells lenalidomide for prescription use under the brand name Revlimid®. (Ex. 1, D.I. 1 at ¶ 25; *see also* Ex. 1, D.I. 1-1, Ex. D.) It is alleged to be a “thalidomide analogue,” but it is not alleged to be thalidomide. (Ex. 1, D.I. 1 at ¶ 25.) In 2005, the FDA approved Revlimid® for treating a condition known as “MDS del-5q.”[3] (*See* Ex. 1, D.I. 1-1, Ex. D at 1.) In 2006, the FDA approved Revlimid®, in combination with dexamethasone, for treating multiple myeloma in patients who have received at least one prior therapy. (*Id.*) And in 2013, the FDA approved Revlimid® for treating mantle cell lymphoma in patients whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. (*Id.*) Andrulis does not allege that use of Revlimid® according to any of its FDA-approved indications infringes the ’346 patent.

3. Alkeran® (Melphalan)

Celgene stopped selling melphalan (Alkeran®) over four years ago, in 2009. (Ex. 1, D.I. 1 at ¶ 17.) Andrulis alleges that melphalan is an alkylating agent. (*Id.* at ¶ 17.) It was approved by the FDA in 1964, and is now approved for use as a palliative treatment for multiple myeloma. (*Id.* at ¶ 15; Ex. 1, D.I. 1-1, Ex. B at 1–2.) Andrulis does not allege that use of Alkeran® according to its FDA-approved indication infringes the ’346 patent.

[3] The full description of this condition is “transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without cytogenetic abnormalities.” (Ex. 1, D.I. 1-1, Ex. D at 1.)

C. Andrulis's Infringement Allegations

Andrulis's Complaint accuses Celgene of direct infringement under 35 U.S.C. § 271(a), and two forms of indirect infringement – contributory infringement under 35 U.S.C. § 271(c) and active inducement under 35 U.S.C. § 271(b). (Ex. 1, D.I. 1 at ¶¶ 81–88.) In particular, Andrulis alleges direct and contributory infringement as follows:

> Upon information and belief, Celgene has directly infringed, induced infringement of, and/or contributed to infringement of one or more claims of the '346 patent, both literally and under the doctrine of equivalents, by making, using, selling, and/or offering for sale Thalomid® and Revlimid® for use with an alkylating agent, e.g., melphalan, to treat cancers, e.g., multiple myeloma. By doing so, Celgene has violated 35 U.S.C. § 271.

(*Id.* at ¶ 84.) As noted above, Andrulis fails to allege that Celgene has treated any patients or otherwise ever used the method of claim 2. Likewise, with respect to contributory infringement, Andrulis does not allege that the products at issue lack substantial non-infringing uses or that Celgene knew they were especially made or adapted for infringing use. Again, Andrulis's Complaint never asserts that any of the FDA-approved uses for the products at issue infringe any claim of the '346 patent.

Andrulis also asserts that Celgene has actively induced infringement:

> Upon information and belief, Celgene has actively induced others, e.g., doctors, to directly infringe one or more claims of the '346 patent. Since at least the receipt of this Complaint, Celgene has acted with knowledge, or at least with willful blindness of the fact, that the induced acts constitute infringement of the '346 patent. Upon information and belief, Celgene has intended to cause direct infringement by others, e.g., doctors. Upon information and belief, Celgene has taken affirmative steps to induce infringement by, among other things, communicating (orally and/or in writing) the advantages or benefits of using thalidomide (Thalomid®) and lenalidomide (Revlimid®) in combination with melphalan (Alkeran®) to treat cancers. Thus, Celgene has aided, abetted, urged, or encouraged others, e.g., doctors, to directly infringe one or more claims of the '346 patent, and Celgene has affirmatively and specifically intended to cause direct infringement.

(Ex. 1, D.I. 1 at ¶ 85.) Andrulis's inducement claim is based on a general "information and belief" allegation that Celgene has communicated the benefits of an off-label use that combines Revlimid® or Thalomid® with an alkylating agent to treat cancers. (*Id.*) As explained below, Andrulis's specific alleged "facts" (*Id.* at ¶¶ 54–74) supporting the general allegation that Celgene encouraged this off-label use are insufficient to support a plausible inference that Celgene did anything of the kind.

Finally, Andrulis alleges willful infringement as follows:

> Upon information and belief, Celgene's acts of infringement of the '346 patent have been willful and deliberate. Since at least the receipt of this Complaint, Celgene has acted with an objectively high likelihood that its actions constituted infringement of the '346 patent by refusing to take a license and continuing to make, sell, and/or promote thalidomide (Thalomid®) and lenalidomide (Revlimid®) in combination with melphalan (Alkeran®) to treat cancers. The objectively defined risk was either known to Celgene or so obvious that it should have been known to Celgene.

(Ex. 1, D.I. 1 at ¶ 86.) Thus, the willful infringement claim is based purely on post-Complaint conduct and a formulaic recitation of the objective and subjective elements of willfulness.

ARGUMENT

I. LEGAL STANDARD

Under Rule 8(a)(2), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief" in order to "give the defendant fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. A pleading requires more than "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

To survive a motion to dismiss, a complaint must contain sufficient factual matter "to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial

plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged . . . . The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556). "Factual allegations [of a complaint] must be enough to raise a right to relief above the speculative level . . . ." *Twombly*, 550 U.S. at 555.

Courts evaluate the sufficiency of the allegations in a complaint at the outset of the litigation because a "basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court." *Id.* at 558. Further, Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 556 U.S. at 678–79.

II. THE COMPLAINT FAILS TO STATE A DIRECT INFRINGEMENT CLAIM

To state a claim for direct infringement, a patentee must, *inter alia*, identify an accused direct infringer's product, process, or method that allegedly "embod[ies] the patented invention." *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1360 (Fed. Cir. 2007); *see also Gevo, Inc. v. Butamax (TM) Advanced Biofuels LLC*, No. 12-1724-SLR, 2013 WL 3381258, at *3 (D. Del. July 8, 2013) (dismissing for failure to plead "any act of infringement that plausibly could be related to [the accused infringer]"). In this case, a claim of direct infringement against Celgene requires identification of a product made, used, sold or imported by Celgene, or a method practiced by Celgene, that allegedly infringes the claims of the '346 patent.

Andrulis does not identify any Celgene product or act that allegedly embodies any of the '346 patent claims. As discussed above, the '346 patent has three claims. Claims 1 and 3 require products that contain both thalidomide and an alkylating agent. Yet, Andrulis does not allege that

any Celgene product contains these two active ingredients. Claim 2 requires treating neoplastic diseases by administering a combination of thalidomide and an alkylating agent to an afflicted mammal. Andrulis does not allege that Celgene treats or administers drugs to patients. Thus, Andrulis's direct infringement claim should be dismissed.

III. THE COMPLAINT FAILS TO STATE A CONTRIBUTORY INFRINGEMENT CLAIM

Contributory infringement occurs if a party sells a product for use in practicing a patent, and that product: (1) is material to practicing the invention; (2) has no substantial non-infringing uses; and (3) is known by the party "to be especially made or especially adapted for use in an infringement of such patent." 35 U.S.C. § 271(c). "To state a claim for contributory infringement . . . a plaintiff must, among other things, plead facts that allow an inference that the components sold or offered for sale have no substantial non-infringing uses." *Bill of Lading*, 681 F.3d at 1337; *see also Superior Indus., LLC v. Thor Global Enters. Ltd.*, 700 F.3d 1287, 1295–96 (Fed. Cir. 2012) (affirming dismissal for failure to allege no substantial non-infringing uses or knowledge that product at issue was especially made or adapted for infringing use); *Pragmatus Telecom, LLC v. Ford Motor Co*., No. 12-92-RGA, 2012 WL 2700495, at *1 (D. Del. July 5, 2012) (dismissing bare allegations of no substantial non-infringing uses).

Andrulis does not allege the elements of contributory infringement in its Complaint, or plead a factual basis for such a claim. In particular, Andrulis does not allege that the products at issue lack substantial non-infringing uses, or that Celgene knew that they were especially made or adapted for an infringing use. Indeed, the attachments to Andrulis's Complaint identify only non-infringing uses as approved uses (Ex. 1, D.I. 1-1, Exs. B–D), and thus, the Complaint tacitly admits that the products at issue have substantial non-infringing uses. *Bill of Lading*, 681 F.3d at 1337 & n.9 (affirming dismissal where attachments to complaint showed that accused infringer's

"products ***do*** have substantial non-infringing uses") (emphasis original); *see also Vita-Mix*, 581 F.3d at 1327 ("substantial non-infringing use" is any use that is "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental"). Accordingly, Andrulis's contributory infringement claim should also be dismissed.

IV. THE COMPLAINT FAILS TO STATE AN INDUCEMENT CLAIM

Section 271(b) provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Courts interpret § 271(b) to require at least the following elements: (1) direct infringement by a third party; (2) an affirmative act by the accused inducer that actively induced the direct infringement; (3) knowledge of the existence of the patent that is allegedly infringed; (4) knowledge that the induced acts constitute patent infringement; and (5) specific intent to encourage another's infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068–2069 (2011); *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1308 (Fed. Cir. 2012) (en banc) (quoting *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc)).

To plead elements (4) and (5) of an active inducement claim, a patentee must allege "facts plausibly showing that [an accused inducer] specifically intended [its] customers to infringe the [] patent and knew that the customer's acts constituted infringement." *Bill of Lading*, 681 F.3d at 1339 (citing *Global-Tech*, 131 S. Ct. at 2068). "Stating that the defendant was on notice of a patent as of a certain date is insufficient to provide a factual basis for alleging knowledge." *HSM Portfolio LLC v. Fujitsu Ltd.*, No. 11-770-RGA, 2012 WL 2580547, at *1 (D. Del. July 3, 2012). Further, "[i]n assessing whether it is reasonable to infer intent . . . a court must assess the facts in the context in which they occurred." *Bill of Lading*, 681 F.3d at 1340 (citation omitted). The general principles of the Supreme Court's decisions in *Twombly* and *Iqbal*

govern the pleading of active inducement. *Id.* at 1336–37. Andrulis's active inducement claim does not measure up to these standards.

A. Andrulis Does Not Sufficiently Allege That Celgene Had The Requisite Knowledge That The Allegedly Induced Acts Infringed

Andrulis's allegation concerning Celgene's purported knowledge that the allegedly induced acts were infringing is limited to a single conclusory sentence:

> Since at least the receipt of this Complaint, Celgene has acted with knowledge, or at least with willful blindness of the fact, that the induced acts constitute infringement of the '346 patent.

(Ex. 1, D.I. 1 at ¶ 85.) This allegation is merely a formulaic, conclusory recital of an element of an active inducement claim. The Supreme Court has held that such conclusory allegations are insufficient to avoid dismissal. *Iqbal*, 556 U.S. at 678. In *Iqbal*, the Court dismissed a discrimination claim because the intent allegation was conclusory. There, the plaintiff contended that the defendant "'knew of, condoned, and willfully and maliciously agreed to subject'" the plaintiff "to harsh conditions of confinement 'as a matter of policy, solely on account of [his] religion, race, and/or national origin and for no legitimate penological interest.'" *Id.* at 680. Andrulis's bare allegation of knowledge of induced infringement is just as conclusory as the insufficient intent allegation in *Iqbal*.[4]

[4] The conclusory allegation that Celgene knew that the allegedly induced acts constitute infringement is particularly strained with respect to Revlimid®, which Andrulis alleges is not thalidomide, but (allegedly) a "thalidomide analogue." (Ex. 1, D.I. 1 at ¶ 77.) Andrulis seemingly asserts only that certain uses of Revlimid® would infringe under the doctrine of equivalents. (*Id.* at ¶¶ 77–79.) There can be no plausible inference that Celgene somehow knew that the use of Revlimid® would infringe the '346 patent under the doctrine of equivalents, and no allegations in the Complaint so state. It is implausible that Celgene knew that the '346 patent covered the use of Revlimid®. Any such allegations would be especially implausible given that, during prosecution, Andrulis surrendered claim coverage extending beyond thalidomide by narrowing the claims, and thus creating prosecution history estoppel. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 736–37 (2002) ("A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112. We must regard the (Continued . . .)

Both the Federal Circuit and this Court have rejected conclusory pleadings of knowledge of induced infringement. *See, e.g.*, *Superior Indus.*, 700 F.3d at 1296 (affirming dismissal where patentee failed to allege facts leading to reasonable inference that accused infringer "knew it had induced acts of infringement"); *HSM*, 2012 WL 2580547, at *1 (dismissing inducement claim where allegations concerning knowledge of induced infringement were "wholly unsupported by any factual allegations"). As this Court held in *HSM*, "[s]tating that the defendant was on notice of a patent as of a certain date is insufficient to provide a factual basis for alleging knowledge" that induced acts constituted infringement. *HSM*, 2012 WL 2580547, at *1. Accordingly, Andrulis's claim for active inducement should be dismissed for failure to allege facts plausibly showing that Celgene knew that it induced acts that constituted infringement.[5]

B. Andrulis Does Not Sufficiently Allege That Celgene Possessed The Specific Intent To Encourage Another's Infringement

Beyond its failure to adequately plead knowledge that the allegedly induced acts constituted infringement, Andrulis's Complaint similarly fails to properly allege that Celgene "possessed specific intent to encourage another's infringement." *Bill of Lading*, 681 F.3d at 1339; *see also Superior Indus.*, 700 F.3d at 1296. Andrulis's general allegation of this element is

(. . . continued.)
patentee as having conceded an inability to claim the broader subject matter or at least as having abandoned his right to appeal a rejection.").

[5] Further, where (as here) a patentee does not limit its cause of action to "post-litigation conduct," the patentee is required to allege pre-suit knowledge that the allegedly induced acts constituted infringement. *Execware, LLC v. Staples, Inc.*, No. 11-cv-836-LPS-SRF, 2012 WL 6138340, at *5 (D. Del. Dec. 10, 2012) (citation omitted). In the alternative, Andrulis's prayer for relief related to damages for activity that took place before the Complaint was filed should be stricken, and Andrulis's claims should be limited to alleged damages for conduct that took place after the Complaint was served.

too conclusory to support specific intent, and its specific allegations do not support a plausible inference of specific intent to encourage infringement.[6]

1. Andrulis's General Allegation Of Specific Intent To Induce Infringement Is Conclusory

Andrulis generally alleges that "Celgene has intended to cause direct infringement by others, e.g., doctors" and that "Celgene has taken affirmative steps to induce infringement by, among other things, communicating (orally and/or in writing) the advantages or benefits of using thalidomide (Thalomid®) and lenalidomide (Revlimid®) in combination with melphalan (Alkeran®) to treat cancers." (Ex. 1, D.I. 1 at ¶ 85.) This conclusory allegation is insufficient to support the specific intent element of an active inducement claim. *Iqbal*, 556 U.S. at 678; *see also Superior Indus.*, 700 F.3d at 1296 (affirming dismissal where patentee did not allege facts to support reasonable inference that accused inducer specifically intended to induce infringement); *Monec Holding AG v. Motorola Mobility, Inc.*, 897 F. Supp. 2d 225, 234 (D. Del. 2012) (finding that patentee's "conclusory averments" that accused inducer "s[old], advertis[ed], suppli[ed] and instruct[ed] its respective customers on the use of the infringing product" were insufficient to establish specific intent).

2. Andrulis's Other Allegations Do Not Support A Plausible Inference Of Specific Intent To Induce Another's Infringement

Aside from its conclusory allegation of specific intent, the Complaint sets forth a number of allegations purportedly in support of the assertion that Celgene induced acts of infringement and specifically intended to do so. (Ex. 1, D.I. 1 at ¶¶ 54–74.) As explained below, the alleged

[6] Andrulis's allegations that Celgene affirmatively acted to induce infringement, and had specific intent to induce infringement, appear to be based on the same set of fact allegations (*i.e.*, ¶¶ 54–74 and 85 of the Complaint). Andrulis's allegations with respect to affirmative acts of inducement (element (2) of an active inducement claim) are insufficient for the same reasons set forth herein with respect to specific intent (element (4) of an active inducement claim).

acts by Celgene do not support a plausible inference that Celgene induced doctors to combine thalidomide with an alkylating agent and acted with specific intent to cause infringement.

(a) The Sale Of A Lawful Product By Lawful Means Cannot, In And Of Itself, Constitute Specific Intent To Induce Infringement

The "sale of a lawful product by lawful means, with the knowledge that an unaffiliated, third party may infringe, cannot, in and of itself, constitute inducement of infringement." *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1276 n.6 (Fed. Cir. 2004) (quoting *Organon Inc. v. Teva Pharms., Inc.*, 244 F. Supp. 2d 370, 380 (D.N.J. 2002)); *see also Vita-Mix*, 581 F.3d at 1329 (instructions on non-infringing uses "provide no basis on which [a patentee] can rely to infer specific intent to encourage infringement"); *Organon*, 244 F. Supp. 2d at 381 (finding no specific intent to induce where "there is a significant market for non-infringing uses of [the accused product].").

Here, Andrulis tacitly concedes that all of the FDA-approved uses for which Celgene markets the products at issue are ***non-infringing***. (Ex. 1, D.I. 1 at ¶¶ 15, 20, 26, 84.) Likewise, the Complaint admits that the prescribing information for Revlimid® and Thalomid® instructs doctors to combine Revlimid® or Thalomid® with dexamethasone, and not with an alkylating agent (such as melphalan). (Ex. 1, D.I. 1-1, Exs. C–D.) In fact, the prescribing information for Revlimid® ***warns*** doctors and patients that combining Revlimid® with melphalan creates a higher risk of new cancer development compared to melphalan alone. (Ex. 1, D.I. 1-1, Ex. D at 60, 83.) Celgene's activities with respect to these non-infringing uses cannot properly form the basis for Andrulis's specific intent allegations. Further, as shown below, Celgene's activities are entirely consistent with these non-infringing uses and do not support a plausible inference of specific intent to induce infringement.

(b) None Of Andrulis's Allegations Forms A Plausible Basis To Infer That Celgene Possessed Specific Intent To Induce Another's Infringement

Andrulis's various allegations concerning Celgene's activities with respect to the products at issue (Ex. 1, D.I. 1 ¶¶ 54–74) do not plausibly show that Celgene specifically intended doctors to infringe the '346 patent. They are either entirely irrelevant or merely involve lawful activities with respect to non-infringing products and uses.

First, Andrulis states that the FDA "sent Celgene at least one warning letter reporting that Celgene engaged in improper marketing activities by stating or suggesting that Thalomid® is safe and effective for an unapproved use, *e.g.*, by utilizing press releases to promote Thalomid®." (*Id.* at ¶ 54.) The letter is irrelevant for several reasons. The letter was issued over 13 years ago (Ex. 2)—well before October 2, 2007, which is the limit of the six-year statutory damages period for this case.[7] 35 U.S.C. § 286. Further, Andrulis does not allege (nor could it) that the letter related to the accused ***combination*** of thalidomide and an alkylating agent. (*See* Ex. 2.) The allegation does not plausibly show that Celgene promoted a combination of thalidomide and an alkylating agent to treat neoplastic diseases and specifically intended to induce infringement.[8]

[7] The letter Andrulis referenced is a public record made available by the FDA at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM165843.pdf (last visited November 19, 2013). The Court may consider the letter without converting this motion to a motion for summary judgment. *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (public records may be referenced in considering motion to dismiss); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) ("[A] 'document . . . explicitly relied upon in the complaint' may be considered" on a motion to dismiss) (quotation omitted).

[8] A similar allegation is made in Paragraph 67 of the Complaint, and it is deficient for the same reasons. There is no allegation that the alleged investigations in 2011 and 2012 were directed to the use of Thalomid® or Revlimid® in combination with an alkylating agent.

Second, Andrulis alleges that Celgene employees have: communicated the benefits of Celgene's products (Ex. 1, D.I. 1 at ¶ 55); discussed the use of Alkeran® to treat cancer (*id.* at ¶ 56); discussed the use of Thalomid® to treat cancer (*id.* at ¶ 57); and discussed the use of Revlimid® to treat cancer (*id.* at ¶ 58). (*See also id.* at ¶¶ 59–60.) None of these allegations asserts that any Celgene employee encouraged (or even mentioned) the use of either Thalomid® or Revlimid® in ***combination with*** Alkeran® or any alkylating agent. Each of these allegations is entirely consistent with, and what one would expect of, a company selling its products for their respective approved uses (which are non-infringing). *Dynacore*, 363 F.3d at 1276 n.6. Further, Andrulis vaguely alleges that these activities took place at "various times" over a fifteen-year time frame, from 1998 to 2013 (*id.* at ¶¶ 56–58), but does not allege any concrete facts about whether these alleged activities occurred before or after October 2, 2007, the limit of the statutory damages period. Accordingly, these allegations are also insufficient to support a plausible inference of specific intent to induce infringement.

Third, Andrulis claims that Celgene gave doctors reprints of certain published articles and other materials. (Ex. 1, D.I. 1 at ¶¶ 61–62, 65.) Andrulis acknowledges, however, that "[d]rug-product manufacturers may now provide doctors with publications concerning unapproved or off-label uses in response to unsolicited requests." (*Id.* at ¶ 44.) Moreover, the FDA guidance referenced in the Complaint provides that the act of providing information about off-label use in such circumstances is not considered "evidence of the firm's intent that its product be used for an unapproved or uncleared use." (Ex. 3, 76 Fed. Reg. 82304.)[9] Andrulis never alleges that Celgene provided the publications in the absence of a doctor request, or

[9] The Court may take judicial notice of materials published in the Federal Register without converting this motion to one for summary judgment. *See* 44 U.S.C. § 1507 ("The contents of the Federal Register shall be judicially noticed.").

anything more about the alleged providing of the publications. Without more information alleged with regard to the circumstances, there can be no plausible inference of a specific intent to cause doctors to administer Thalomid® or Revlimid® in combination with an alkylating agent, particularly in view of Andrulis's allegation that doctors exercise their own judgment when prescribing the use of FDA-approved drugs. (Ex. 1, D.I. 1 at ¶ 41.)[10]

Fourth, Andrulis alleges that Celgene issued press releases about clinical studies and foreign regulatory actions concerning the combination of Thalomid® or Revlimid® with an alkylating agent. (Ex. 1, D.I. 1 at ¶¶ 63–64.) That is also irrelevant. Andrulis does not allege that the clinical studies or foreign regulatory approvals themselves were in any manner improper. Nor does Andrulis allege any facts that would plausibly support that the unidentified and unquoted press releases show specific intent on the part of Celgene to induce infringement. For example, one would expect an international company to publicly report on relevant business developments in foreign countries. Likewise, Andrulis does not allege whether the press releases were issued before or after October 2, 2007, or whether any doctor acted in response to any of the press releases.

Fifth, Andrulis alleges, "upon information and belief," that "the use of melphalan and prednisone together with thalidomide (Thalomid®) to treat multiple myeloma increased disproportionately to the number of new cases of multiple myeloma in the United States from the early 2000s to the mid 2000s." (Ex. 1, D.I. 1 at ¶ 71.) A similar allegation is made with respect to Revlimid®. (*Id.* at ¶ 72.) From these allegations, Andrulis surmises that the alleged trend is due to "efforts by Celgene . . . to encourage doctors to treat multiple myeloma with these drug

[10] Andrulis also contends that doctors who have been funded by Celgene have reported favorable results from clinical trials. (Ex. 1, D.I. 1 at ¶ 66.) This conclusory and unsupported allegation is irrelevant to Andrulis's claim that Celgene allegedly induced infringement because Andrulis does not allege that the acts of those doctors are attributable to Celgene.

products." (*Id.* at ¶ 74.) These speculative "trend" allegations do not show a plausible connection between alleged acts by doctors and any act or specific intent by Celgene to encourage the ***combination of*** Thalomid® or Revlimid® ***with*** Alkeran®. Celgene's promotion of Thalomid®, Revlimid®, and Alkeran® for their respective approved uses (including to treat multiple myeloma)—uses which are all non-infringing—does not plausibly show that the claimed combination was promoted or intended. This is particularly so in view of Andrulis's own allegations that organizations other than Celgene have been advocating for the combination of thalidomide and melphalan. (*See, e.g.*, *id.* at ¶ 36.) And yet again, Andrulis's vague allegations rely on alleged acts before October 2, 2007, stretching beyond the reach of the statutory damages period. (*See id.* at ¶¶ 68, 71–73.)

In short, Andrulis's active inducement allegations wither under scrutiny. When Andrulis's allegations are scrutinized and placed in context—as they must be when considering a motion to dismiss, *Bill of Lading*, 681 F.3d at 1340—they fail to plausibly support a claim for active inducement of infringement. According to Andrulis's own allegations, Celgene has marketed Thalomid®, Revlimid®, and Alkeran® for non-infringing uses. Andrulis offers no concrete factual allegations plausibly supporting its claim that Celgene specifically intended to induce infringement by doctors through an off-label use. Instead, Andrulis seeks to have its Complaint serve as a ticket for a "fishing expedition" in search of a factual basis for its claim of active inducement. That is improper—Rule 8 does not "unlock the doors of discovery" for such speculative allegations. *Iqbal*, 556 U.S. at 678–79. Andrulis's active inducement claim should be dismissed.

V. THE COMPLAINT FAILS TO STATE A CLAIM FOR WILLFULNESS

To plead willful infringement, a patentee must allege facts plausibly showing that the accused "infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc). "If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk . . . was either known or so obvious that it should have been known to the accused infringer." *Id.* "[W]hen a complaint is filed, a patentee must have a good faith basis for alleging willful infringement. . . . So a willfulness claim asserted in the original complaint must necessarily be grounded exclusively in the accused infringer's pre-filing conduct." *Id.* at 1374 (citing Fed. R. Civ. P. 8, 11(b)).

A patentee must "plead facts giving rise to at least a showing of objective recklessness of the infringement risk." *Execware*, 2012 WL 6138340, at *6 (citation omitted). That is, the patentee must "demonstrate[] a link between the various allegations of knowledge of the patents-in-suit and the allegations that the risks of infringement" were either known or were so obvious that they should have been known. *Id.* (citation omitted); *see also Chalumeau Power Sys. LLC v. Alcatel-Lucent*, No. 11-1175-RGA, 2012 WL 6968938, at *2 (D. Del. July 18, 2012).

The only allegation in the Complaint of willful infringement is conclusory and relies exclusively on alleged post-filing facts. (Ex. 1, D.I. 1 at ¶ 86.) Accordingly, any claim based on pre-filing activities should be dismissed. *See Seagate*, 497 F.3d at 1374. In any event, Andrulis's allegations regarding the objective and subjective elements of willfulness are so conclusory and

formulaic that they fail the *Iqbal* standard.[11] *Iqbal*, 556 U.S. at 678; *see also Chalumeau*, 2012 WL 6968938, at *2. Accordingly, the willfulness claim should be dismissed in its entirety.

CONCLUSION

For the foregoing reasons, Celgene's motion to dismiss the Complaint should be granted. The Complaint fails to state a claim upon which relief may be granted.

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[11] Andrulis's conclusory willful infringement claim is particularly implausible with respect to Revlimid®, which is accused of infringement only under the doctrine of equivalents. As explained *supra* in footnote 4, it is implausible to infer based on facts pled by Andrulis that Celgene knew (or that it should have been obvious to Celgene) that the '346 patent covered the use of Revlimid®.